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Healthcare Compliance Forms and Tools
Sample Minimal Risk Research Guidance Summary

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Research, Discovery, and Innovation	Minimal Risk Research

Projects approved under this guidance are reviewed according to the organization's guidance for review of projects that are not federally funded or supported or regulated by the Food and Drug Administration (FDA). Human research that is not federally funded or supported, or FDA regulated, and does not significantly affect the health and welfare of participants can be deemed minimal risk.

Determination of a project's review level requires a determination by a designated institutional review board (IRB) member. Investigators *cannot* make determinations whether human research projects meet the regulatory criteria.

Submission Requirements

Submission of an "Application for Human Research" is required to make a determination. The Human Subjects Protection Program (HSPP) and designated IRB members will review the request. The investigator will receive a formal letter of determination.

Informed Consent

Obtaining informed consent from participants fulfills the ethical requirements of "respect for persons" discussed in the Belmont Report. Minimal risk projects, therefore, are still required to obtain informed consent from subjects, provided in a language that subjects understand. It is not necessary to obtain written consent so long as participants are informed.

Potential subjects should have all the information regarding the study (e.g., purpose, procedures, risks and benefits, and contact information) prior to agreeing to participate in the study, but the consent does not need to meet the regulatory requirements found in the federal rule. Please see the informed consent templates on the HSPP website for more on developing consents.